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Subject:	COMMISSION REGULATION (EU) No .../.. of XXX amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, indoxacarb and pyraclostrobin in or on certain products (Text with EEA relevance)

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Delegations will find attached document D029075/02.

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Encl.: D029075/02



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[...](2013) **XXX** draft

**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

**amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, indoxacarb and pyraclostrobin in or on certain products**

(Text with EEA relevance)

**COMMISSION REGULATION (EU) No .../..**

**of XXX**

**amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, indoxacarb and pyraclostrobin in or on certain products**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC<sup>1</sup>, and in particular Article 14(1)(a) thereof,

Whereas:

- (1) For dimethomorph, indoxacarb and pyraclostrobin maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance dimethomorph on seeds of spices (except nutmeg) and on caraway fruits, an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) As regards indoxacarb, such an application was made for cress, land cress, red mustard, other lettuce and salad plants, purslane, beet leaves and other spinach and similar (leaves). As regards pyraclostrobin, such an application was made for Jerusalem artichokes.
- (4) In accordance with Article 8 of Regulation (EC) No 396/2005 these applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

- (5) The European Food Safety Authority, hereinafter ‘the Authority’, assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs<sup>2</sup>. It forwarded these opinions to the Commission and the Member States and made them available to the public.
- (6) For all applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances via consumption of all food products that may contain those substances, nor the short-term exposure due to high consumption of the relevant crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.
- (7) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the relevant requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (8) As regards dimethomorph, indoxacarb and pyraclostrobin, MRLs were set for several commodities by Commission Regulation (EU) No 668/2013 of 12 July 2013<sup>3</sup>. As that Regulation applies as of 2 February 2014, it is appropriate for the MRLs provided for by this Regulation, to apply from the same date.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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<sup>2</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>:  
Reasoned opinion on the modification of the existing MRLs for dimethomorph in seeds of spices and caraway. EFSA Journal 2013;11(2):3126 [27 pp.]. doi:10.2903/j.efsa.2013.3126.

Reasoned opinion on the modification of the existing MRLs for indoxacarb in various salad plants and in spinach-like plants. EFSA Journal 2013;11(5):3247 [31 pp.]. doi:10.2903/j.efsa.2013.3247.

Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in cucumbers and Jerusalem artichokes. EFSA Journal 2013;11(2):3109 [27 pp.]. doi:10.2903/j.efsa.2013.3109.

<sup>3</sup> Commission Regulation (EU) No 668/2013 of 12 July 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, dimethomorph, indoxacarb, and pyraclostrobin in or on certain products (OJ L 192, 13.7.2013, p. 39).

*Article 1*

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 2 February 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*José Manuel BARROSO*

## ANNEX

In Annex II to Regulation (EC) No 396/2005, the columns for dimethomorph, indoxacarb and pyraclostrobin are replaced by the following:

[For Official Journal: insert table Annex II existing].